MAY 01 2002

K021217

Arox Passive-Fixation, Bipolar, Endocardial Pacing Lead Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:
Proprietary Name: Arox Leads
Classification: Class III (21 CFR 870.3680(b))
Classification Name: Cardiovascular Permanent Pacemaker Electrode
Product Code: DTB

Date Prepared: April 16, 2002

General Description:
The BIOTRONIK Arox lead is a bipolar, passive-fixation, endocardial pacing lead available in straight and "J"-shaped configurations, for placement in the ventricle or atrium. The designation Arox xx-BP refers to Arox straight leads, which are available in lengths (xx) of 53 or 60 cm; Arox xx-JBP refers to Arox "J"-shaped leads, which are available in lengths of 45 and 53 cm.

The Arox xx-JBP model has a permanent bend proximal to both lead electrodes, resulting in the distal portion of the lead body having what is commonly referred to as a "U" or "J" shape. This lead shape facilitates placement in the right atrial appendage.

Arox xx-BP and Arox xx-JBP leads feature four silicone tines for passive-fixation in the heart's trabeculae. The tip electrode is made of a platinum/iridium base material, with a fractal iridium surface and electrically active surface area of 3.5 mm^2. The ring electrode is made of a platinum/iridium base material, with a fractal iridium surface and electrically active surface area of 22.6 mm^2. The lead conductor consists of quadrifilar MP35N wire in a coaxial configuration, insulated with silicone rubber tubing. All Arox leads utilize a 3.2 mm IS-1 connector.

Device Modification:
The Arox leads introduced in this Special 510(k) notification are modified versions of BIOTRONIK's currently marketed Merox leads (#K010281, dated 04-09-02). The modifications are a change in the tip electrode surface area from 1.3 mm^2 to 3.5 mm^2 and a change in the shape of the tip from segmented to lenticular. The tip electrode surface area size and shape are identical to BIOTRONIK's currently marketed Polyrox family of passive-fixation, endocardial leads (#K000763, dated 04-06-00).

Predicate Devices:
BIOTRONIK proposes the following leads cleared through 510(k) notifications as predicate devices for the Arox leads:

- BIOTRONIK's Merox passive-fixation, endocardial leads (#K010281, dated 04-09-02)
- BIOTRONIK's Polyrox passive-fixation, endocardial leads (#K000763, dated 04-06-00)

Indication for Use:
Arox bipolar, passive-fixation, endocardial pacing leads (Arox xx-BP and Arox xx-JBP) are intended to provide permanent pacing and sensing in the atrium and or ventricle when used with a compatible pulse generator.

Name and Address of Manufacturing Site:
BIOTRONIK GmbH & Co. (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

Contact Person(s) and Phone Number:
Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374 Fax (503) 635-9936

Name and Address of Contract Manufacturing Site:
BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland
011-41-1-864-5169

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 1 2002

Mr. Jon Brumbaugh
Director of Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K021217
Trade Name: Arox Passive-Fixation, Bipolar Pacemaker Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Permanent Pacemaker Electrode
Regulatory Class: Class III (three)
Product Code: DTB
Dated: April 16, 2002
Received: April 17, 2002

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

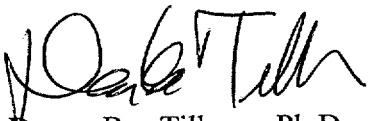
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021217

Device Name: Arox Passive-Fixation, Bipolar Pacemaker Lead

Indications For Use:

Arox bipolar, passive-fixation, endocardial pacing leads (Arox xx-BP and Arox xx-JBP) are intended to provide permanent pacing and sensing in the atrium and or ventricle when used with a compatible pulse generator.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021217